REMARKS/ARGUMENTS

In this Amendment, claims 22-68 are pending and claims 32, 43, and 44 are currently amended. No new matter has been added.

Indefiniteness Rejections are Overcome

Claim 22 was rejected as being indefinite for the term "reduced sensitivity to penetrating moisture." On page 7 of the specification, reduced sensitivity is defined as follows:

> The invention therefore relates to the use of magnesium stearate for improving the resistance to moisture, i.e. for lowering the sensitivity to atmospheric humidity, of dry powder formulations for inhalation. The use of magnesium stearate accordingly brings about an improvement in the storage stability and in particular a reduction of the influence of penetrating moisture on FPF (and the FPD), which permits the maintenance of a high FPD and FPF even under comparatively extreme temperature and humidity compositions.

This definition would lead one skilled in the art to understand the meaning of the term "reduced sensitivity to penetrating moisture." Accordingly, applicants submit that the term is clear.

Claim 32 was rejected as being indefinite regarding confusion about the Markush group. This claim has been amended and applicants submit that the claim is now clear.

Claim 43 was rejected as being indefinite. This claim has been amended to delete from the preamble the statement "against penetrating moisture." Applicants submit that this claim is now clear, especially focusing on the statement at the end of the claims which reads, "which is present in an amount effective to stabilize the FPF of the formulation against penetrating moisture."

Claim 44 was rejected as being indefinite. This claim was amended so that reduced moisture sensitivity now describes the dry powder formulation. Applicants submit that this claim is now clear, given the argument set forth above for claim 22.

Claim 58 was rejected as being indefinite for the term "improved resistance to moisture." As set forth in the arguments above for claim 22, given the disclosure in the specification, one skilled in the art would clearly understand the meaning of this term. Applicants submit, therefore, that this claim is clear.

Obviousness Rejections are Overcome

Claims 44-64 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Staniforth (Respiratory Drug Delivery II) in view of Carling (WO 93/11773). Applicants note that claims 22-43 and 65-68 are no longer subject to art rejections and believe that with the above amendments and remarks regarding indefiniteness, these claims are now allowable.

The Examiner's position is that claims 44-64 are obvious over the combination of Staniforth (disclosing powder formulations comprising an active agent in small particle size and a carrier particle in large size and magnesium stearate as an additive) and Carling (disclosing formoterol and budesonide for inhalation in the treatment of respiratory disorders). Applicants traverse.

Claims 44-64 are directed to dry powder formulations with improved moisture resistance and inhalers for delivery of same. Applicants' formulations comprise a pharmaceutically inactive carrier, a pharmaceutically active component comprising particles of inhalable size and magnesium stearate, in an amount effective to provide the dry powder formulation with reduced sensitivity to penetrating moisture. The admixture of carrier, active component, and magnesium stearate as ingredients in Applicants' dry powder formulation is especially suitable for use in dry powder inhalers, which are typically subject to the adverse effects of moisture.

Claims 44-57 and 62-64 are directed to a dry powder inhaler. In contrast to the present invention, Staniforth's cited meeting presentation paper is directed to a study of the properties and the complex forces and interactions that bind particles together in dry powder formulations. However, no reference is made to this combination of ingredients in a dry powder inhaler. Carling does not cure this deficiency. Accordingly, the combination of

Staniforth and Carling does not render obvious present claims 44-57 and 62-64, directed to a dry powder inhaler. Applicants respectfully request that this rejection be withdrawn.

Claims 58-61 are directed to a dry powder formulation for inhalation. Staniforth does not disclose use of its formulation in a dry powder inhaler. Without the disclosure of the use in an inhaler, it would not be obvious for one skilled in the art to use the disclosed formulation in an inhaler. Fundamentally, when a skilled artisan considers a formulation for inhalation, the skilled artisan never considers the powder formulation alone. The product that the patient uses is that formulation in a device.

The problem of the deleterious effects of moisture on dry powder formulations has been known for many years, and it was a problem faced by the present inventors. It follows that when looking for solutions to the problems associated with atmospheric moisture on formulations contained in devices, the skilled person would turn not to Staniforth, as Staniforth does not disclose the use of inhalers. The skilled person would also appreciate that the formulation would have to be stabilized in device for long periods of storage and during patient usage. In the latter case, devices used by patients may be held in conditions of elevated temperatures and humidity.

Skilled artisans would not be led to combine Staniforth with Carling, because Staniforth does not disclose the use of inhalers. If a skilled artisan were interested in using a formulation with an inhaler, he would not be led to Staniforth. One skilled in the art would not be led to combine Staniforth's teaching with that of Carling so as to achieve a stabilized, inhalable and magnesium stearate-containing dry formulation having both reduced sensitivity to moisture and stability during storage in an inhaler without additional types of moisture-proofing. Absent a teaching, suggestion, or incentive in the art to support the combination, obviousness cannot be established. Accordingly, applicants respectfully submit that the present invention is a non-obvious solution to the problem of protecting formulations in device against the rigors of moisture over prolonged periods of time.

CONCLUSION

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. With the enclosed three month extension of time, this response is due on or before August 21, 2006. The Commissioner is hereby authorized to charge payment of any fees that may be required, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 28069-606 CON.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39, 529
Naomi S. Biswas, Reg. No. 38,384
Attorneys for Applicant
MINTZ, LEVIN
Tel: 617-542-6000
Fax: 617-542-2241
Customer No. 30623

Date: August 21, 2006